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GEICO Casualty Company*

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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GOVERNMENT EMPLOYEES INSURANCE
COMPANY, GEICO INDEMNITY COMPANY,
GEICO GENERAL INSURANCE COMPANY and
GEICO CASUALTY COMPANY,

Plaintiffs,

-against-

21st CENTURY PHARMACY, INC.,
ALBERT ALISHAYEV,
AZU AJUDUA, M.D.,
STARRETT CITY MEDICAL, P.C.,
VARUZHAN DOVLATYAN, M.D.,
MT. VERNON MEDICAL ONE, P.L.L.C.,
ANDRE DUHAMEL, M.D.,
MORRIS PARK PRIMARY MEDICAL CARE, P.C.,
NOEL HOWELL, M.D.,
KINGSTON MEDICAL, P.C.,
EDNAN SALAHUDDIN SHEIKH, M.D. and
ACTIVE MEDICAL CARE, P.C.,

Defendants.

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COMPLAINT

Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company,
GEICO General Insurance Company and GEICO Casualty Company (collectively, “GEICO” or
“Plaintiffs”), as and for their Complaint against the Defendants, hereby allege as follows:

Docket No.: ____ ()

**Plaintiffs Demand a Trial
by Jury**

NATURE OF THE ACTION

1. This action seeks to recover approximately \$2,559,000.00 that the Defendants wrongfully have stolen from GEICO by submitting, and causing to be submitted, thousands of fraudulent claims seeking payment for pharmaceutical products that primarily include (i) topical compounded products (“Compounded Products”), and (ii) Terocin patches, Lidoderm patches and Flector patches (collectively, “Pain Patches”) (the Compounded Products and Pain Patches are hereinafter collectively referred to as “Fraudulent Pharmaceuticals”). The Defendants, as part of a massive scheme to exploit New York’s “No-Fault” system, purport to provide the Fraudulent Pharmaceuticals to individuals involved in automobile accidents and eligible for insurance coverage under policies of insurance issued by GEICO (“Insureds”).

2. 21st Century Pharmacy, Inc. (“21st Century”) and its alleged owner, Albert Alishayev (“Alishayev”), purport to be a neighborhood pharmacy, but 21st Century produces and dispenses large quantities of the Compounded Products that are not approved by the United States Food and Drug Administration (“FDA”), in set formulations, without tailoring the medications to the individual needs of any individual patient, and without complying with licensing requirements that are designed to ensure the quality, safety and effectiveness of manufactured drug products. 21st Century’s large scale pharmaceutical compounding production business has billed GEICO alone nearly \$10 million in less than 2½ years, pursuant to invalid, duplicitous and formulaic prescriptions, and likely has billed the rest of the New York automobile insurance industry tens of millions of dollars more for the mass produced Compounded Products.

3. To implement their massive fraudulent scheme, 21st Century and Alishayev entered into collusive arrangements involving the payment of unlawful kickbacks to various licensed physicians and their professional medical corporations, which render medical services to

Insureds from multidisciplinary “clinics” located throughout the New York City area (the “No-Fault Clinics”), in order to have them issue, or purport to issue, formulaic and unnecessary prescriptions, primarily for Compounded Products, which are in turn used by the Defendants to generate tens of millions of dollars in fraudulent billing to GEICO and other New York insurers.

4. 21st Century, while purporting to be a neighborhood pharmacy, is violating FDA oversight and New York State licensing laws by working collusively with various physicians, including those who are named as defendants herein, and having the physicians prescribe the Compounded Products and other Fraudulent Pharmaceuticals pursuant to a pre-determined fraudulent treatment protocol whereby, in many instances, 21st Century obtains authorization to bill for the pharmaceuticals allegedly dispensed to a particular patient *before the physician prescribes the Fraudulent Pharmaceuticals or even determines the patient's need for such products*. This is consistent with the fact that the Fraudulent Pharmaceuticals are produced by 21st Century in mass quantities, are not medically necessary, and are provided solely to financially enrich the Defendants, rather than to treat or otherwise benefit the Insureds who purportedly receive them.

5. In addition to recovering damages resulting from this massive fraudulent scheme, GEICO seeks a declaration that it is not legally obligated to pay 21st Century approximately \$6,211,000.00 in pending fraudulent claims the Defendants submitted or caused to be submitted through 21st Century because:

- (i) 21st Century engaged in illegal compounding by producing and dispensing vast quantities of the Compounded Products in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault benefits;
- (ii) the Fraudulent Pharmaceuticals were not medically necessary and were provided – to the extent they were provided at all – pursuant to pre-determined fraudulent treatment protocols designed solely to financially

enrich the Defendants, rather than to treat or otherwise benefit the Insureds who purportedly received them;

- (iii) the Defendants participated in illegal, collusive relationships in which licensed physicians prescribed the medically unnecessary Fraudulent Pharmaceuticals in exchange for unlawful kickbacks paid by 21st Century and its alleged owner Alishayev;
- (iv) the Defendants made false and fraudulent misrepresentations to GEICO by submitting or causing to be submitted charges for Fraudulent Pharmaceuticals provided pursuant to invalid, duplicitous and formulaic prescriptions; and
- (v) the Defendants made false and fraudulent misrepresentations to GEICO concerning the maximum permissible charges for the Fraudulent Pharmaceuticals allegedly provided to Insureds in order to induce GEICO to reimburse 21st Century under the New York “No-Fault” laws for benefits to which it is not entitled.

6. The Defendants fall into the following categories:

- (i) 21st Century is a New York corporation engaged in a fraudulent scheme in which it purports to dispense the Fraudulent Pharmaceuticals to GEICO Insureds and then submits bills to GEICO and other New York automobile insurers for reimbursement to which it is not entitled;
- (ii) Alishayev is the purported owner of 21st Century (21st Century and Alishayev are hereinafter collectively referred to as the “Pharmacy Defendants”); and
- (iii) Azu Ajudua, M.D. (“Ajudua”), Starrett City Medical Care, PC, Varuzhan Dovlatyan, M.D. (“Dovlatyan”), Mt. Vernon Medical One PLLC, Andre Duhamel, M.D. (“Duhamel”), Morris Park Primary Medical Care, PC, Noel Howell, M.D. (“Howell”), Kingston Medical, PC, Ednan Salahuddin Sheikh, M.D. (“Sheikh”) and Active Medical Care, PC (collectively, the “Prescribing Defendants”) are physicians along with professional corporations listed under their names, who, in exchange for kickbacks, routinely prescribe, or purport to prescribe, the medically unnecessary Fraudulent Pharmaceuticals that are dispensed by 21st Century.

7. The Defendants’ scheme began in 2013 and continues uninterrupted to the present day. As discussed more fully below, the Defendants at all times have known that: (i) the Fraudulent Pharmaceuticals are not medically necessary and are provided pursuant to pre-determined fraudulent treatment and billing protocols designedly solely to enrich the Defendants;

(ii) 21st Century unlawfully manufactures, produces, and dispenses the Compounded Products on a large scale and in set formulations, in violation of state and federal regulatory and licensing requirements; (iii) claims submitted for reimbursement are based on invalid, duplicitous and formulaic prescriptions; (iv) the Fraudulent Pharmaceuticals are prescribed pursuant to unlawful kickback arrangements between the Pharmacy Defendants and licensed physicians; and (v) the charges submitted exceed the maximum permissible charges for the pharmaceutical products actually dispensed to Insureds.

8. As such, 21st Century does not now have – and never had – any right to be compensated for the Fraudulent Pharmaceuticals allegedly dispensed to GEICO insureds. The chart attached hereto as **Exhibit “1”** sets forth a representative sample of the fraudulent claims that have been identified to-date which the Defendants submitted, or caused to be submitted, to GEICO. As a result of the Defendants’ scheme, GEICO has incurred damages of approximately \$2,559,000.00

THE PARTIES

I. Plaintiffs

9. Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company, and GEICO Casualty Company are Maryland corporations with their principal places of business in Chevy Chase, Maryland. GEICO is authorized to conduct business and to issue policies of automobile insurance in the State of New York.

II. Defendants

10. Defendant 21st Century is a New York corporation with its principal place of business at 96-05 57th Avenue, Corona, New York, through which the Fraudulent Pharmaceuticals have been billed to insurance companies, including GEICO. 21st Century was

incorporated on December 19, 2012, and from November 2013 through the present day, knowingly has submitted fraudulent claims to GEICO and continues to seek reimbursement on hundreds of unpaid fraudulent claims.

11. 21st Century is registered with New York State as a pharmacy, but is not registered as a manufacturer or outsourcing facility.

12. Defendant Alishayev is a citizen of New York and a registered nurse who owns and controls 21st Century.

13. Defendant Ajudua resides in and is a citizen of New York. Dr. Ajudua was licensed to practice medicine in New York on April 22, 1977, and knowingly has participated in a scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds.

14. Defendant Starrett City Medical PC is a New York medical professional corporation allegedly owned by Ajudua, which was incorporated on or about July 21, 2015, has its principal place of business at 105-10 Flatlands Avenue, Brooklyn, New York, and was used by the Defendants as part of the fraudulent scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds.

15. Defendant Dovlatyan resides in and is a citizen of New Jersey. Dr. Dovlatyan was licensed to practice medicine in New York on August 15, 1997, and knowingly has participated in a scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds.

16. Defendant Mt. Vernon Medical One PLLC is a New York medical professional corporation allegedly owned by, among others, Dovlatyan, which was incorporated on or about September 12, 2014, has its principal place of business at 2 Wilson Place, Mt. Vernon, New York, and was used by the Defendants as part of the fraudulent scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds.

17. Defendant Duhamel resides in and is a citizen of New York. Dr. Duhamel was licensed to practice medicine in New York on May 12, 1993, and knowingly has participated in a scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds. Upon information and belief, Defendant Duhamel also maintains a residence in Haiti and is often there for extensive periods of time.

18. Defendant Morris Park Primary Medical Care PC is a New York medical professional corporation allegedly owned by Duhamel, which was incorporated on or about January 21, 2011, has its principal place of business at 799 Morris Park Avenue, Bronx, New York, and was used by the Defendants as part of the fraudulent scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds. Morris Park Primary Medical One PC is not currently registered with the New York Office of the Professions, but nevertheless is allegedly actively treating patients.

19. Defendant Howell resides in and is a citizen of New Jersey. Dr. Howell was licensed to practice medicine in New York on June 30, 2000, and knowingly has participated in a scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds.

20. Defendant Kingston Medical PC is a New York medical professional corporation allegedly owned by Howell, which was incorporated on or about January 23, 2015, has its principal place of business at 205-20 Jamaica Avenue, Hollis, New York, and was used by the Defendants as part of the fraudulent scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds.

21. Defendant Sheikh resides in and is a citizen of New Jersey. Dr. Sheikh was licensed to practice medicine in New York on April 24, 2009, and knowingly has participated in a scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds.

22. Defendant Active Medical Care PC is a New York medical professional corporation allegedly owned by Sheikh, which was incorporated on or about May 14, 2014, has its principal place of business at 1500 Astor Avenue, Bronx, New York, and was used by the Defendants as part of the fraudulent scheme to prescribe the Fraudulent Pharmaceuticals to hundreds of GEICO Insureds

JURISDICTION AND VENUE

23. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1332(a)(1) because the matter in controversy exceeds the sum or value of \$75,000.00, exclusive of interest and costs, and is between citizens of different states. Pursuant to 28 U.S.C. § 1331, this Court also has jurisdiction over the claims brought under 18 U.S.C. §§ 1961 et seq., the Racketeer Influenced and Corrupt Organizations (“RICO”) Act, because they arise under the laws of the United States. In addition, this Court has supplemental jurisdiction over the subject matter of the claims asserted in this action pursuant to 28 U.S.C. § 1367.

24. Venue in this District is appropriate pursuant to 28 U.S.C. § 1391, as the Eastern District of New York is the District where one or more of the Defendants reside and because this is the District where a substantial amount of the activities forming the basis of the Complaint occurred.

ALLEGATIONS COMMON TO ALL CLAIMS

I. An Overview of New York’s No-Fault Laws

25. GEICO underwrites automobile insurance in the State of New York.

26. New York’s “No-Fault” laws are designed to ensure that injured victims of motor vehicle accidents have an efficient mechanism to pay for and receive the healthcare services that they need. Under New York’s Comprehensive Motor Vehicle Insurance Reparations Act (N.Y. Ins. Law §§ 5101 et seq.) and the regulations promulgated pursuant thereto (11 N.Y.C.R.R. §§

65 et seq.)(collectively, referred to herein as the “No-Fault Laws”), automobile insurers are required to provide Personal Injury Protection Benefits (“No-Fault Benefits”) to Insureds.

27. No-Fault Benefits include up to \$50,000.00 per Insured for necessary expenses that are incurred for health care goods and services.

28. An Insured can assign his or her right to No-Fault Benefits to the providers of healthcare services in exchange for those services. Pursuant to a duly executed assignment, a healthcare provider may submit claims directly to an insurance company and receive payment for necessary goods and medical services provided, using the claim form required by the New York State Department of Insurance (known as the “Verification of Treatment by Attending Physician or Other Provider of Health Service,” or, more commonly, as an “NF-3”). In the alternative, healthcare providers sometimes submit claims using the Health Care Financing Administration insurance claim form (known as the “HCFA-1500 Form”).

29. Pursuant to New York’s No-Fault Laws (11 N.Y.C.R.R. § 65-3.16(a)(12)), a healthcare provider is not eligible to receive No-Fault Benefits if it fails to meet any applicable New York state or local licensing requirement necessary to perform such services in New York.

30. In State Farm Mut. Auto. Ins. Co. v. Mallela, 4 N.Y.3d 313 (2005), the New York Court of Appeals, relying on the implementing regulation, 11 N.Y.C.R.R. § 65-3.16(a)(12), made clear that healthcare providers that fail to comply with licensing requirements are ineligible to collect No-Fault benefits. The Court of Appeals further provided that insurers may look beyond a facially-valid license to determine whether there was a failure to abide by state and local law.

31. Pursuant to New York Insurance Law § 403, the NF-3s and HCFA-1500 Forms submitted by a healthcare provider to GEICO, and to all other automobile insurers, must be verified by the health care provider subject to the following warning:

Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime.

II. An Overview of The Applicable Licensing Laws

32. The United States Federal Food, Drug, and Cosmetic Act (“FDCA”) authorizes the United States Food and Drug Administration (“FDA”) to oversee the safety of food, drugs, and cosmetics.

33. The FDA strictly regulates over-the-counter and prescription drugs, and oversees drug manufacturing in several ways, including testing drugs and routinely inspecting drug manufacturing plants and outsourcing facilities engaged in the compounding of drugs.

34. Pursuant to New York Education Law § 6808, no person, firm, corporation or association shall possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling or manufacturing, or shall offer drugs, prescriptions or poisons for sale at retail or wholesale unless registered by the New York State Department of Education as a pharmacy, wholesaler, manufacturer or outsourcing facility.

35. Manufacturers and outsourcing facilities that seek to register with the New York State Department of Education, as required by New York State Education Law § 6808, must also register with the FDA and be listed as a manufacturer or outsourcing facility on the FDA website.

36. Pursuant to Education Law § 6530(38), it is unlawful and/or professional misconduct for a licensed physician to enter into an arrangement or agreement with a pharmacy for the compounding and/or dispensing of coded or specially marked prescriptions, while Education Law § 6811 makes it a crime for any person to enter into an agreement with a

physician (or other licensed healthcare provider) for the compounding or dispensing of secret formula (“coded”) prescriptions.

37. Pursuant to Education Law § 6530(18), it is unlawful and/or professional misconduct for a licensed physician to “directly or indirectly” offer, give, solicit, receive or agree to receive any fee or other consideration to or from a third party in exchange for patient referrals or in connection with the performance of professional services.

38. Pursuant to Education Law § 6509-a, it is professional misconduct under certain circumstances for a licensee to “directly or indirectly” request, receive, or participate in the division, transference, assignment, rebate, splitting, or refunding of a fee in connection with professional care or services including services related to drugs and/or medications.

39. Pursuant to 8 N.Y.C.R.R. § 29.1(b)(3) a licensee is precluded from “directly or indirectly” offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or client or in connection with the performance of professional services.

III. An Overview of Compounded Products

40. Pursuant to Section 503A of the Federal Food, Drug and Cosmetic Act (“FDCA”), as amended by the Compounding Quality Act, the laws applicable to drugs regulated by the FDA, including the laws relating to the safe manufacturing of drugs, generally do not apply to a compounded drug product: (1) if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order that a compounded product is necessary for the identified patient, and (2) if the compounding is by a licensed pharmacist in a state licensed pharmacy.

41. The FDA defines traditional pharmacy compounding as the combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to

a licensed practitioner's prescription. Traditional pharmacy compounding plays a role in providing access to medications for patients with unique medical needs, which cannot otherwise be met with a commercially available product. Pharmacy compounding of specified medications may be appropriate when an FDA-approved drug product is not available or appropriate for a patient, including strength or route of delivery.

42. Compounded drugs are generally not FDA approved, though they may include FDA approved drugs, and are generally exempt from the FDA approval process which applies to new drugs if the drug is compounded for an identified individual patient based on the receipt of a valid prescription, approved by the prescribing practitioner on the prescription order, that a compounded product is necessary for the identified patient. See, 21 U.S.C. § 353a.

43. When Compounded Products meet the requirements of 21 U.S.C. § 353a and are compounded for an individual patient, they can be exempted from the requirement, among others, that they be FDA approved. See, 21 U.S.C. § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to... this section is effective with respect to such drug”).

44. The FDA has publicly expressed concern about large-scale drug manufacturing under the guise of pharmacy compounding.

45. When Congress adopted 21 U.S.C. § 353a, its express intent was to “ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing [of drugs that would otherwise require FDA approval] under the guise of compounding.” H.R. Rep. No. 105-399, at 94 (1997) (Conf. Rep.)(emphasis added). As Congress stated at the time:

the “exemptions in [this section] are limited to compounding for an individual patient based on the medical need of such patient for the particular drug compound. To qualify for the exemptions, *the pharmacist or physician must be*

able to cite to a legitimate medical need for the compounded product that would explain why a commercially available drug product would not be appropriate. Although recording the medical need directly on each prescription order would not be required, this technique would be one of many acceptable ways of documenting the medical need for each compounded drug product. This medical need would not include compounding drugs that are essentially copies of commercially available drug products for largely economic reasons. The pharmacist may rely on appropriately documented input from the physician as to whether a commercially available drug product is not appropriate for the identified individual patient."

S. Rep. No. 105-43, at 67-68 (1997)(emphasis added).

46. Because Compounded Products are not FDA approved, and therefore, not subject to FDA regulations regarding quality, safety and effectiveness of manufactured drug products, they should never be prescribed as a matter of routine therapy, and should only be prescribed to meet a legitimate specific need of an individual patient, or when all other forms of oral and/or topical medications approved for the treatment of pain have failed.

47. Prior to receiving a prescription for any Compounded Product, a patient's medical records should document all other forms of FDA approved drugs that were prescribed and failed to treat the symptom for which the Compounded Product was then prescribed, and/or the medical rationale that supports the otherwise premature prescription of a Compounded Product.

48. Recently, the prescription of Compounded Products and ensuing billing to both private and public insurers has been the subject of state and federal investigations and litigation due to increased concerns regarding fraud. For example, in August 2016, the United States Attorney for the Southern District of New York arrested and indicted more than 40 members of the Genovese, Gambino, Luchese, and Bonanno crime families, whose alleged illegal activities included "causing...corrupt doctors to issue unnecessary and excessive prescriptions for expensive compound cream" billed to insurers. See USA v. Parrello, 16 Crim. 522 (2016). See

also U.S. Department of Health & Human Services, Office of Inspector General, *High Part D Spending on Opioids and Substantial Growth in Compound Drugs Raise Concerns*, HHS OIG Data Brief, OEI-16-00290 (June 2016); Office of Inspector General, United States Postal Services, *Worker's Compensation Compound Drug Costs, Management Advisory*, Report No. HR-MA-16-003 (March 14, 2016). The USPS OIG attributed fraud as one of the causes for the “unprecedented increases” in compound drug costs and referenced the “alarming discovery” of physicians prescribing compound drugs to patients whom they never examined, and fraud schemes involving physicians prescribing medically unnecessary compound drugs in exchange for kickbacks. *Id.*

IV. The Defendants' Fraudulent Scheme Involving The Fraudulent Pharmaceuticals

49. Beginning in 2013, and continuing uninterrupted through the present day, the Defendants masterminded and implemented a fraudulent scheme in which the Defendants have used 21st Century to bill exorbitant amounts to the New York automobile insurance industry for reimbursement – which it is not eligible to receive – of the Fraudulent Pharmaceuticals purportedly provided to Insureds.

50. Despite purporting to be a neighborhood pharmacy, 21st Century is engaged in illegal compounding and operating as a large-scale manufacturer, producer, and dispenser of mass quantities of compounded drugs in set formulations, as part of arrangements it makes with licensed physicians to compound and dispense specially marked, formulaic prescriptions.

51. The Defendants purport to provide the massive quantities of Fraudulent Pharmaceuticals produced by 21st Century to Insureds pursuant to valid prescriptions, but the Fraudulent Pharmaceuticals are prescribed, dispensed and billed pursuant to the Defendants' pre-determined, fraudulent treatment and billing protocol.

52. Specifically, pursuant to the Defendants' fraudulent scheme, and in exchange for unlawful kickbacks, various licensed physicians, operating from No-Fault Clinics that treat thousands of Insureds, purport to prescribe medically unnecessary and illusory pharmaceutical products to the Insureds, which in turn permit the Defendants to bill GEICO for the Fraudulent Pharmaceuticals under the name of 21st Century.

53. An essential aspect of the Defendants' scheme is that the Pharmacy Defendants present 21st Century as a legitimate, neighborhood pharmacy even though it is in direct violation of New York State and Federal regulatory and licensing requirements that govern drug manufacturers and outsourcing facilities and which prohibit collusive arrangements for compounding and/or dispensing of coded or specially marked prescriptions – all of which poses a huge threat to the health and safety of the patients and general public.

54. The Fraudulent Pharmaceuticals produced by 21st Century (i) are not medically necessary; (ii) are often duplicative of other medications prescribed to the Insureds; (iii) contain a combination of ingredients that produce no significant difference between the compounded drug and comparable commercially available products; (iv) are almost never prescribed properly under the governing regulations; and (v) are "prescribed" by physicians and produced by 21st Century in massive quantities without regard to medical necessity or the regulations governing the appropriate use of Compounded Products, as part of unlawful kickback arrangements.

55. In short, the Fraudulent Pharmaceuticals produced by 21st Century, and prescribed by the physicians working in collusion with 21st Century, serve no purpose other than to support exorbitant charges to New York automobile insurers and exploit the Insureds' No-Fault benefits.

A. 21st Century is Engaged in Large Scale Compounding Activity in Violation of New York State and Federal Law Governing Drug Manufacturers and Outsourcing Facilities and is Engaged in Fraudulent Prescription Practices

56. As stated above, Compounded Products are only appropriate in limited circumstances, should be formulated for an individual patient's needs upon receipt of a valid prescription for an identified individual or a notation on a prescription stating that a Compounded Product is necessary for the identified patient, and should not be prescribed and dispensed as a matter of course.

57. 21st Century, however, is blatantly exploiting the No-Fault insurance reimbursement system by entering into collusive relationships with licensed physicians and professional corporations in order to produce and dispense the same set of Compounded Product formulations again and again to thousands of Insureds involved in minor fender-bender type accidents, in order to generate tens of millions of dollars in fraudulent billing to insurers.

58. 21st Century, acting under the guise of a neighborhood pharmacy, gives the Prescribing Defendants and other licensed physicians what amounts to a set product list disguised as a "prescription form" from which the prescribing physicians allegedly choose what pre-determined and premade product(s) should be given to the Insureds.

59. Specifically, the Pharmacy Defendants created and distributed a pre-printed "checklist-type" form bearing 21st Century's name, address, and contact information (the "Fraudulent Scripts"), which list several different pre-determined and mass produced Compounded Products that the prescribing physician can select by placing a checkmark or an "X" in any of the designated boxes. A representative sample of the standard "prescription" forms used to prescribe the Fraudulent Pharmaceuticals to Insureds, and which the Defendants submit to GEICO in support of their fraudulent billing, are annexed hereto as **Exhibit "2"**.

60. These Fraudulent Scripts, used by many of the Prescribing Defendants, identify certain “General Pain Lotions” and/or Compounded Products for “Neuropathic and Other Conditions,” which the Pharmacy Defendants mass produce. The ingredients as well as the quantities of each ingredient to be included in the Compounded Product are predetermined and listed on the Fraudulent Scripts.

61. Each Compounded Product appears in a separate box that lists what condition the Compounded Product supposedly treats accompanied by a code designated by 21st Century for that particular Compounded Product – essentially, the product name – along with the included ingredients and respective quantities. For example, the first “General Pain Lotion” box states “GP1. Musculoskeletal Pain” followed by “Baclofen 4%, Tetracaine 2%, Ketorolac 0.5%, Diclofenac 3%, Verapamil 6%.”

62. While some of the Fraudulent Scripts contain a section entitled “Special Formulations” indicating the prescribing physician may prescribe an individualized Compounded Product, the prescribing physicians never do so. This section of the Fraudulent Scripts is merely a façade to give the appearance of legitimacy and the impression that the Defendants provide individual Compounded Products as opposed to or in addition to the mass produced products listed.

63. On those occasions when one of 21st Century’s Fraudulent Scripts is not used, the prescribing physicians’ scripts, rather than containing a handwritten, individualized prescription, often use a pre-printed label or a stamp that designates on the prescription form what predetermined and mass produced Compounded Product is being prescribed.

64. 21st Century and the Compounded Products are not exempt from FDA oversight and approval, and similar New York state licensing requirements applicable to drug manufacturers and outsourcing facilities, because the Compounded Products are clearly not

individualized and tailored to meet specific individual patient needs; are not provided pursuant to legitimate prescriptions; and are illegally compounded in set formulations in vast quantities. See, 21 U.S.C. § 355 and 21 U.S.C. 353a(a).

65. Indeed, as part of the fraudulent scheme, the prescribing physicians never prescribe, and 21st Century never dispenses, individually tailored Compounded Products, made for an identified individual Insured, which produce a significant difference between the compounded drug and a comparable commercially available product.

66. The prescribing physicians also never recommend that the Insureds first try over-the-counter FDA approved topical medications and assess their effectiveness, prior to prescribing the Fraudulent Pharmaceuticals produced and dispensed by 21st Century in mass quantities.

67. 21st Century is not acting as a neighborhood pharmacy, which may legally compound a particular drug necessary for an individual patient, but rather is acting as a large-scale manufacturer, producer, and dispenser of several mass produced Compounded Products and is deliberately circumventing state and federal regulations designed to protect the health and safety of patients.

68. In keeping with the fact that 21st Century is engaged in the large-scale production and manufacturing of Compounded Products, 21st Century has billed GEICO alone nearly \$10 million over 2-1/2 years for, among other things, thousands and thousands of allegedly customized Compounded Products that 21st Century purports to create on a case-by-case basis.

69. In keeping with the fact that 21st Century is engaged in the large-scale production and manufacturing of Compounded Products, 21st Century's billing to GEICO, for patients with coverage under New York's No-Fault automobile insurance system, is in addition to both (i) 21st Century's billing to other New York automobile insurance companies, and (ii) 21st Century's billing to Workers' Compensation insurance companies.

70. In fact, 21st Century has advised that most of its business relates to patients who have coverage under Workers' Compensation insurance; meaning that the thousands of supposedly customized Compounded Products that 21st Century allegedly prepared on a case-by-case basis for GEICO Insureds represents only a portion of the pharmaceutical products it has allegedly prepared and dispensed.

71. Notwithstanding the volume of Fraudulent Pharmaceuticals allegedly prepared and dispensed by 21st Century, the Pharmacy Defendants claim that 21st Century customizes each Compounded Product "one at a time"; that each individual Compounded Product is "made to order" in response to each individual prescription; and that 21st Century takes approximately one hour to mix a single Compounded Product.

72. Despite the foregoing, 21st Century has repeatedly submitted billing to GEICO for in excess of ten (10) allegedly "individual" Compounded Products prepared in a single day – and sometimes even twenty-five (25) allegedly "individual" Compounded Products prepared in a 24-hour period.

73. Given that GEICO's Insureds make up only a fraction of the New York insurance market; that 21st Century claims that the majority of its business relates to patients with Workers Compensation insurance; and that 21st Century utilizes a pre-printed "checklist-type" prescription form steering physicians to prescribe set formulations of Compounded Products, it is axiomatic that the Pharmacy Defendants, contrary to their claims, mass produce the Compounded Products in bulk as opposed to compounding individual prescriptions on a case-by-case basis upon receipt of a valid prescription order.

74. 21st Century is plainly not a neighborhood pharmacy filling an occasional prescription for a customized medication that may be necessary when an FDA-approved drug product is not available or appropriate for a patient. It is instead an illegal producer and

dispenser of mass quantities of Compounded Products, made without regard to the specific needs of any particular patient as part of illegal, collusive relationships with physicians, in violation of federal and state law.

75. By engaging in these abusive tactics and misrepresenting 21st Century to be a neighborhood pharmacy, the Pharmacy Defendants have violated material regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities thereby allowing the Defendants to submit or cause to be submitted tens of millions of dollars in claims to the New York automobile insurance industry for reimbursement for Fraudulent Pharmaceuticals to which they were not entitled, while risking the health and safety of the patients.

76. Furthermore, as drug manufacturers and dispensers, the Pharmacy Defendants are also in violation of 21 U.S.C. § 355(a) which states that “no person shall introduce or deliver for introduction into interstate commerce any new drug” without first obtaining approval to do so by way of an application filed with the Secretary with respect to that drug.

77. A “new drug” – as defined by 21 U.S.C. § 321(p)(1) – is “any drug...the composition of which is such that such drug is not generally recognized...as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof.”

78. 21st Century’s Compounded Products – for which it has billed the New York automobile insurance industry tens of millions of dollars – are not FDA approved and, therefore, not verified by the FDA as being safe, effective or quality products, and are recognized neither as safe nor effective. In fact, the use of Compounded Products exposes Insureds to risks including harmful contraindications, which is why they should only be prescribed under unique circumstances.

B. The Illegal, Collusive Kickback Arrangements Between 21st Century and the Prescribing Physicians

79. In furtherance of the fraudulent scheme, the Defendants participate in illegal, collusive arrangements in which the Prescribing Defendants named herein, among others, prescribe the medically unnecessary Fraudulent Pharmaceuticals in exchange for unlawful kickbacks paid by 21st Century and its record owner Alishayev.

80. 21st Century, in fact, arranges with various No-Fault Clinics that treat thousands of Insureds, to have the licensed physicians operating therefrom, prescribe, or purport to prescribe, medically unnecessary and illusory pharmaceutical products to the Insureds, which in turn permit the Pharmacy Defendants to bill GEICO for the Fraudulent Pharmaceuticals under the name of 21st Century.

81. In exchange for kickbacks paid by the Pharmacy Defendants to the Prescribing Defendants, the Prescribing Defendants automatically prescribe, or purport to prescribe, the Fraudulent Pharmaceuticals to patients of the No-Fault Clinics pursuant to the Defendants' fraudulent pre-determined treatment and billing protocol, without regard to genuine patient care, without regard to pharmacologic outcomes, and without regard to cost and attention to fiscal responsibility.

82. In exchange for kickbacks paid by the Pharmacy Defendants to the Prescribing Defendants, the Prescribing Defendants automatically prescribe, or purport to prescribe, the Fraudulent Pharmaceuticals to patients of the No-Fault Clinics pursuant to invalid, illegal and/or formulaic "prescriptions," which are nothing more than a "cover" for the predetermined issuance of large volumes of mass produced pharmaceuticals designed to exploit the patients' No-Fault insurance benefits.

83. The Prescribing Defendants prescribe, or purport to prescribe, the Fraudulent Pharmaceuticals to patients of the No-Fault Clinics, despite their knowledge that the Fraudulent Pharmaceuticals are not customized or tailored to the individual needs of a particular patient; despite their knowledge that there are FDA approved drugs available and appropriate for the particular patients; and despite their knowledge that the Fraudulent Pharmaceuticals are prescribed in huge volumes without regard to genuine patient care, without regard to pharmacologic outcomes, and without regard to cost and attention to fiscal responsibility.

(i) **The Predetermined Fraudulent Prescription of the Fraudulent Pharmaceuticals**

84. Pursuant to the No-Fault Laws, in order for a healthcare provider to be eligible for reimbursement of No-Fault Benefits, it must be in possession of a valid assignment of benefits from the patient. See, 11 N.Y.C.R.R. § 65-3.11.

85. A healthcare provider would not need an Insured to execute a No-Fault Assignment of Benefits form (“AOB”) unless it intends to provide the Insured with healthcare services and to seek reimbursement for those services directly from New York automobile insurers.

86. Logically, a pharmacy would not need an Insured to execute an AOB, authorizing the pharmacy to bill for pharmaceutical services from a New York automobile insurer, until it has received a valid prescription from a prescribing physician who has determined that the patient is in need of a prescribed medication to be dispensed by the pharmacy.

87. In keeping with the fact that the Defendants prescribe Compounded Products as part of a kickback arrangement involving a pre-determined fraudulent treatment protocol, the Defendants direct patients to execute AOBs to 21st Century in many cases well before the

prescribing physicians have even prescribed the Compounded Products or even determined the patient's need for a purportedly customized Compounded Product.

88. Specifically, 21st Century obtained AOBs to allow the Pharmacy Defendants to bill for pharmaceuticals provided to particular patients of the Prescribing Defendants prior to the patient even receiving a prescription for the Fraudulent Pharmaceuticals. A representative sample of AOBs obtained by 21st Century is annexed hereto as **Exhibit "3"**.

89. Examples of 21st Century obtaining an AOB prior to the patient receiving a prescription include the following:

<u>Claimant</u>	<u>Claim Number</u>	<u>Date of Accident</u>	<u>Date of AOB</u>	<u>Date of Prescription</u>	<u>Prescribing Physician Defendant</u>
J.P.	0506310460101019	5/15/2015	5/18/2015	7/27/2015	Sheikh
L.V.	0506310460101019	5/15/2015	5/18/2015	7/6/2015	Sheikh
W.C.	0506310460101019	5/15/2015	5/18/2015	7/27/2015	Sheikh
L.L.	0509282850101015	5/19/2015	6/1/2015	8/17/2015	Sheikh
B.G.	0457676450101030	5/11/2015	5/29/2015	7/31/2015	Sheikh
M.S.	0132340820101070	5/24/2015	6/1/2015	7/13/2015	Sheikh
C.R.	0443514380101019	2/27/2015	3/2/2015	7/27/2015	Sheikh
A.G.	0500990790101015	3/27/2015	3/30/2015	6/29/2015	Sheikh
F.R.	0091338640101147	4/26/2015	4/27/2015	7/27/2015	Sheikh
J.V.	0514925870101018	4/29/2015	5/5/2015	7/27/2015	Sheikh
A.G.	0418743000101049	5/2/2015	5/8/2015	6/29/2015	Sheikh
K.R.	0513238820101018	4/25/2015	4/30/2015	7/6/2015	Sheikh
F.M.	0497278980101028	5/5/2015	5/15/2015	7/6/2015	Sheikh
B.J.	0507399300101015	5/10/2015	5/13/2015	7/27/2015	Sheikh
D.V.	0216827880101031	5/12/2015	5/28/2015	7/20/2015	Sheikh
W.Q.	0509533910101035	5/22/2015	5/26/2015	7/6/2015	Sheikh
M.M.	0132310820101070	5/14/2015	5/19/2015	7/20/2015	Sheikh
A.B.	0532346740101013	6/8/2015	6/9/2015	6/15/2015	Sheikh
J.R.	0295832510101108	5/24/2015	6/9/2015	8/24/2015	Sheikh
F.R.	0501163690101068	5/31/2015	6/1/2015	6/15/2015	Sheikh
P.R.	0501163690101068	5/31/2015	6/1/2015	6/15/2015	Sheikh
I.H.	0421131540101064	6/16/2015	6/18/2015	7/27/2015	Sheikh
S.J.	0509282850101015	5/19/2015	6/3/2015	7/27/2015	Sheikh
B.C.	0509282850101015	5/19/2015	6/3/2015	7/27/2015	Sheikh
C.A.	0516322380101027	6/11/2015	6/15/2015	7/27/2015	Sheikh
S.W.	0325401580101010	6/14/2015	6/19/2015	6/29/2015	Sheikh
D.T.	0274795880101039	6/13/2015	6/18/2015	6/29/2015	Sheikh
S.H.	0399013620101081	6/30/2015	7/2/2015	7/6/2015	Sheikh

G.L.	0457558450101014	6/29/2015	6/30/2015	7/28/2015	Sheikh
L.L.	0457558450101014	6/29/2015	6/30/2015	7/6/2015	Sheikh
N.S.	0425948830101017	6/15/2015	6/22/2015	7/6/2015	Sheikh
K.S.	0179718140101066	8/2/2015	8/3/2015	8/10/2015	Sheikh
W.R.	0412432480101028	5/8/2015	8/10/2015	8/11/2015	Sheikh
T.Z.	0419279580101041	8/28/2015	8/28/2015	8/31/2015	Sheikh
O.R.	0425948830101017	6/15/2015	6/22/2015	7/6/2015	Sheikh
H.B.	0532346740101013	6/8/2015	6/9/2015	7/13/2015	Sheikh
R.N.	0336547370101128	5/24/2015	5/28/2015	7/1/2015	Howell
B.W.	0338673220101056	5/11/2015	5/12/2015	5/25/2015	Howell
P.S.	0363095200101039	5/3/2015	5/13/2015	5/25/2015	Howell
N.D.	0427025980101028	7/19/2015	7/25/2015	8/4/2015	Howell
K.T.	0428532480101134	10/30/2015	11/3/2015	11/13/2015	Howell
H.D.	0446785990101022	4/3/2015	5/5/2015	6/4/2015	Howell
S.J.	0469709560101024	4/21/2015	4/28/2015	5/3/2015	Howell
S.S.	0470065310101021	10/30/2015	11/2/2015	11/13/2015	Howell
A.J.	0539225420101019	7/23/2015	7/23/2015	8/4/2015	Howell
W.N.	0534471650101015	7/15/2015	8/18/2015	8/27/2015	Howell
J.T.	0540345480101019	11/18/2015	12/7/2015	12/14/15	Howell
D.R.	0519651890101011	12/26/2015	12/28/2015	1/6/2016	Howell
K.L.	0441020350101015	1/2/2016	1/4/2016	1/18/2016	Howell
D.O.	0499311150101029	7/11/2015	7/11/2015	7/14/2015	Ajudua

90. Further, in many instances, 21st Century received an AOB to allow it to bill for pharmaceuticals provided to a particular patient not only before the prescription was written, but also before an initial evaluation of the patient was even conducted by the prescribing physician.

91. Examples of 21st Century having obtained an AOB authorizing the Pharmacy Defendants to bill for Fraudulent Pharmaceuticals dispensed to a particular patient prior to the patient undergoing an initial evaluation with the prescribing physician include the following:

<u>Claimant</u>	<u>Claim Number</u>	<u>Date of Accident</u>	<u>Date of AOB</u>	<u>Date of Initial Evaluation</u>	<u>Prescribing Physician Defendant</u>
A.G.	0500990790101015	3/27/2015	3/30/2015	4/6/2015	Sheikh
J.V.	0514925870101018	4/29/2015	5/5/2015	5/11/2015	Sheikh
A.G.	0418743000101049	5/2/2015	5/8/2015	6/18/2015	Sheikh
K.R.	0513238820101018	4/25/2015	4/30/2015	5/11/2015	Sheikh
F.M.	0497278980101028	5/5/2015	5/15/2015	5/18/2015	Sheikh
B.J.	0507399300101015	5/10/2015	5/13/2015	5/18/2015	Sheikh
D.V.	0216827880101031	5/12/2015	5/28/2015	5/29/2015	Sheikh
W.Q.	0509533910101035	5/22/2015	5/26/2015	5/29/2015	Sheikh

<u>Claimant</u>	<u>Claim Number</u>	<u>Date of Accident</u>	<u>Date of AOB</u>	<u>Date of Initial Evaluation</u>	<u>Prescribing Physician Defendant</u>
M.M.	0132310820101070	5/14/2015	5/19/2015	6/1/2015	Sheikh
A.B.	0532346740101013	6/8/2015	6/9/2015	6/15/2015	Sheikh
J.R.	0295832510101108	5/24/2015	6/9/2015	6/15/2015	Sheikh
F.R.	0501163690101068	5/31/2015	6/1/2015	6/15/2015	Sheikh
P.R.	0501163690101068	5/31/2015	6/1/2015	6/15/2015	Sheikh
I.H.	0421131540101064	6/16/2015	6/18/2015	6/22/2015	Sheikh
S.J.	0509282850101015	5/19/2015	6/3/2015	6/22/2015	Sheikh
B.C.	0509282850101015	5/19/2015	6/3/2015	6/22/2015	Sheikh
C.A.	0516322380101027	6/11/2015	6/15/2015	6/22/2015	Sheikh
S.W.	0325401580101010	6/14/2015	6/19/2015	6/29/2015	Sheikh
D.T.	0274795880101039	6/13/2015	6/18/2015	6/29/2015	Sheikh
S.H.	0399013620101081	6/30/2015	7/2/2015	7/6/2015	Sheikh
G.L.	0457558450101014	6/29/2015	6/30/2015	7/6/2015	Sheikh
L.L.	0457558450101014	6/29/2015	6/30/2015	7/6/2015	Sheikh
N.S.	0425948830101017	6/15/2015	6/22/2015	7/6/2015	Sheikh
K.S.	0179718140101066	8/2/2015	8/3/2015	8/10/2015	Sheikh
W.R.	0412432480101028	5/8/2015	8/10/2015	8/11/2015	Sheikh
T.Z.	0419279580101041	8/28/2015	8/28/2015	8/31/2015	Sheikh
O.R.	0425948830101017	6/15/2015	6/22/2015	7/6/2015	Sheikh
H.B.	0532346740101013	6/8/2015	6/9/2015	7/13/2015	Sheikh
R.N.	0336547370101128	5/24/2015	5/28/2015	6/2/2015	Howell
P.S.	0363095200101039	5/3/2015	5/13/2015	5/14/2015	Howell
N.D.	0427025980101028	7/19/2015	7/25/2015	7/27/2015	Howell
H.D.	0446785990101022	4/3/2015	5/5/2015	6/4/2015	Howell
S.S.	0470065310101021	10/30/2015	11/2/2015	11/3/2015	Howell
E.H.	0470065310101021	10/30/2015	11/2/2015	11/3/2013	Howell
S.S.	0446785990101022	4/3/2015	5/5/2015	6/23/2015	Howell
A.J.	0539225420101019	7/23/2015	7/23/2015	8/4/2015	Howell
J.T.	0540345480101019	11/18/2015	12/7/2015	12/14/15	Howell
K.T.	0428532480101134	10/30/2015	11/3/2015	N/A	Howell
J.D.	0537644750101013	7/30/2015	7/30/2015	N/A	Dovlatyan
G.B.	0537644750101013	7/30/2015	7/30/2015	N/A	Dovlatyan
A.O.	0537644750101013	7/30/2015	7/30/2015	N/A	Dovlatyan
N.P.	0536037650101012	7/12/2015	7/8/2015	7/14/2015	Ajudua
D.O.	0499311150101029	7/11/2015	7/11/2015	7/14/2015	Ajudua

92. But for the payment of kickbacks and the predetermined treatment protocol, 21st

Century would not receive an AOB to bill before a prescription was written and/or before an initial evaluation of the patient was even conducted by the prescribing physician.

93. In addition to the foregoing, in a number of instances the Fraudulent Script itself predates the initial evaluation allegedly performed by the prescribing physician.

94. Moreover, often times the Fraudulent Scripts are undated in a willful attempt to evade detection by GEICO that the prescriptions were generated prior to the Insured's initial evaluation.

95. Even more egregious, many Insureds received prescriptions for the Fraudulent Pharmaceuticals without ever having been evaluated whatsoever by the prescribing physician.

96. In further keeping with the fact that the Fraudulent Pharmaceutical are prescribed pursuant to kickback arrangements involving a pre-determined fraudulent billing and treatment protocol, in many instances 21st Century obtained, on the same date, AOBs from multiple Insureds, of different ages and suffering from different types and levels of injury, who were then provided with prescriptions on or about the same date, for the same Fraudulent Pharmaceutical products, merely because they were involved in the same motor vehicle accident.

97. For example, 21st Century obtained AOBs, on or about the same dates, relating to the following Insureds involved in the same accidents, and then provided these Insureds with the same Fraudulent Pharmaceuticals, based on prescriptions dated on or about the same date:

<u>Claimant</u>	<u>Claim Number</u>	<u>Date of Accident</u>	<u>Date of AOB</u>	<u>Date of Script</u>	<u>Prescribing Physician Defendant</u>	<u>Fraudulent Pharmaceuticals Prescribed</u>
S.C.	0332594170101068	7/28/15	7/31/15	7/31/15	Sheikh	GP6
L.N.	0332594170101068	7/28/15	7/31/15	7/31/15	Sheikh	GP6
J.D.	0537644750101013	7/30/15	7/30/15	8/11/15	Dovlatyan	GP4, Terocin Patches
G.B.	0537644750101013	7/30/15	7/30/15	8/11/15	Dovlatyan	GP4, Terocin Patches
A.O.	0537644750101013	7/30/15	7/30/15	8/11/15	Dovlatyan	GP4, Terocin Patches
H.D.	0446785990101022	4/3/15	5/5/15	5/5/15	Howell	NP3; Terocin Patches
S.S.	0446785990101022	4/3/15	5/5/15	N/A	Howell	NP3; Terocin Patches
K.C.	0446917420101021	6/2/15	7/3/15	7/2/15	Howell	NP3; Terocin

<u>Claimant</u>	<u>Claim Number</u>	<u>Date of Accident</u>	<u>Date of AOB</u>	<u>Date of Script</u>	<u>Prescribing Physician Defendant</u>	<u>Fraudulent Pharmaceuticals Prescribed</u>
						Patches
J.O.	0446917420101021	6/2/15	7/2/15	7/2/15	Howell	NP3; Terocin Patches
N.C.	0449434730101029	5/9/15	5/25/15	5/25/15	Howell	NP3; Terocin Patches
J.T.	0449434730101029	5/9/15	5/25/15	5/25/15	Howell	NP3; Terocin Patches
E.H.	0470065310101021	10/30/15	11/2/15	N/A	Howell	NP3; Lidoderm Patches
S.S.	0470065310101021	10/30/15	11/2/15	11/3/15	Howell	NP3; Lidoderm Patches
R.A.	0537811450101011	9/2/15	9/27/15	9/21/15	Howell	NP3; Lidoderm Patches
J.L.	0537811450101011	9/2/15	9/16/15	9/16/15	Howell	NP3; Lidoderm Patches
C.J.	0243700480101015	5/30/15	7/8/15	6/29/15; 7/27/15	Dovlatyan	GP8 (6/29); GP4 (7/27)
S.B.	0243700480101015	5/30/15	7/7/15	6/29/15; 7/27/15	Dovlatyan	GP8 (6/29); GP4 (7/27)
J.B.	0534234510101017	9/10/15	10/1/15	9/28/15; 11/11/15; 1/6/16	Ajudua	Terocin Patches, Naproxen, Nexium ¹ on each date of service
M.S.	0534234510101017	9/10/15	10/2/15	9/28/15; 11/11/15; 1/6/16	Ajudua	Terocin Patches, Naproxen, Nexium on each date of service
A.C.	0455426620101060	9/11/15	9/26/15	9/17/15	Duhamel	GP1; Terocin Patches
C.J.	0455426620101060	9/11/15	9/25/15	9/17/15	Duhamel	GP1; Terocin Patches
W.A.	0481313810101043	11/18/15	N/A	22/24/15	Duhamel	GP1; Terocin Patches
D.L.	0481313810101043	11/18/15	12/18/15	11/24/15	Duhamel	GP1; Terocin Patches
A.S.	0493902190101023	11/28/15	12/10/15	12/1/15	Duhamel	GP1; Terocin Patches
D.A.	0493902190101023	11/28/15	12/9/15	Undated	Duhamel	GP1; Terocin Patches

98. But for the collusive kickback arrangements among the Pharmacy Defendants and the prescribing physicians, 21st Century would not obtain executed AOBs to bill for Fraudulent

¹ Nexium is a heartburn medication. Notably, the evaluation reports for neither Claimant J.B. nor M.S. indicated a history of heartburn.

Pharmaceuticals, allegedly provided to particular patients with unique medical needs, prior to the prescriptions being written and/or before the patient has even undergone a physical examination; there would not be Fraudulent Scripts dated prior to the prescribing physician performing an initial evaluation; and there would not be multiple Insureds, with differing ages, injuries, and health backgrounds, receiving prescriptions on the same dates for the same Fraudulent Pharmaceuticals merely because they were involved in the same accident.

99. The Defendants' conduct in connection with the AOBs, Fraudulent Scripts, and billing, provide clear evidence that: (i) the Fraudulent Pharmaceuticals are not medically necessary and are provided and billed for pursuant to a pre-determined fraudulent billing and treatment protocol; (ii) the Compounded Products are not individually tailored to meet a unique need of a particular patient in response to a valid prescription and, therefore, not FDA exempt; (iii) the Pharmacy Defendants and the prescribing physicians are engaged in collusive kickback arrangements; and (iv) 21st Century is not a neighborhood pharmacy, but a large scale manufacturer and producer of pre-determined, mass produced drug products acting in violation of law.

100. The Defendants' conduct further demonstrates a gross and dangerous indifference to patient care and safety.

101. As part of the scheme, the Insureds are never given the scripts to fill themselves at a pharmacy of their choosing.

102. The Insureds are generally given the Fraudulent Pharmaceuticals directly from the front desk staff at the various No-Fault Clinics without ever seeing the actual prescription. Alternatively, 21st Century purports to mail the Fraudulent Pharmaceuticals directly to the Insureds' homes, again without the patient ever receiving the actual written prescription.

103. When allegedly mailed, 21st Century purports to mail the Fraudulent Pharmaceuticals via Federal Express and submits a delivery confirmation with its bills which alleges the patient signed for the Fraudulent Pharmaceuticals.

104. Often times, the Fraudulent Pharmaceuticals are left on the doorsteps of the Insureds, many of whom have denied ever signing a delivery confirmation.

105. Often times, the Insureds are not even aware they are to receive any medications until they are given the Fraudulent Pharmaceuticals by the front desk staff or receive a package in the mail.

(ii) The Fraudulent and Illegal Scripts in Violation Of Law

106. As part of the scheme to permit 21st Century to produce and bill for mass quantities of the Fraudulent Pharmaceuticals, the Pharmacy Defendants generate pre-printed Fraudulent Scripts that are routinely used by licensed physicians to prescribe the Fraudulent Pharmaceuticals. These “prescriptions,” which are invalid and would not be accepted by any legitimate pharmacy, each list nine to thirteen different pre-printed, pre-formulated Compounded Product prescriptions, each containing multiple drugs, along with several different types of Pain Patches.

107. New York law prohibits the Prescribing Defendants from writing prescriptions on these types of forms with multiple pre-determined Compounded Products that physicians may choose from, and prohibits the Pharmacy Defendants from filling prescriptions pursuant to such forms.

108. Specifically, New York Education Law § 6810(7) provides as follows:

“No prescription for a drug written in this state by a person authorized to issue such prescription shall be on a prescription form which authorizes the dispensing or compounding of any other drug. No drug shall be dispensed by a pharmacist when such prescription form includes any other drug.”

Further, the Education Law prohibits pharmacists from dispensing drugs when the corresponding prescription includes any other drugs. Id.

109. Moreover, as of April 19, 2006, to combat the growing problem of prescription fraud, N.Y. Public Health Law requires that all prescriptions written in New York State – for both controlled and non-controlled substances – must be written on an official serialized New York State prescription bearing the prescriber’s signature as well as the legible, conspicuous imprinted or stamped name of the authorized prescribing healthcare provider. See, N.Y. Public Health Law § 281, see also N.Y. Education Law § 6810(8).

110. The Fraudulent Scripts used by the Defendants are invalid and illegal in that they are not official serialized New York State prescriptions bearing the legible, conspicuous imprinted or stamped name of the authorized prescribing healthcare provider.

111. The Fraudulent Scripts used by the Defendants are invalid and illegal in that they often contain no information other than the patient’s name and address and an indication of which Fraudulent Pharmaceutical is to be billed by 21st Century. A representative sample is annexed hereto as **Exhibit “4”**.

112. The Fraudulent Scripts used by the Defendants are invalid and illegal in that many of them *are not even signed by the purported prescribing physician*. A representative sample is annexed hereto as **Exhibit “5”**.

113. The Fraudulent Scripts contain a section entitled “Prescriber Authorization” in which the prescribing physician is supposed to sign the prescription and fill in information such as the prescriber’s name, address and phone and facsimile numbers; National Provider Identifier (“NPI”) number (a unique 10-digit identification number issued to healthcare providers by the Centers for Medicare and Medicaid Services); Drug Enforcement Agency (“DEA”) number; license number; and the relevant patient diagnosis code(s).

114. The majority of the Fraudulent Scripts submitted to GEICO are missing most, if not all, of the aforementioned information. See, **Exhibit “4”**.

115. Additionally, in violation of N.Y. Education Law § 6810(6)(a), none of the Fraudulent Scripts contain the following requisite language: “THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW.”

116. Notably, the Defendants’ violations of the aforementioned provisions of N.Y. Education Law § 6810 are criminal acts. See, N.Y. Education Law § 6811(19).

117. Moreover, the Prescribing Defendants’ prescriptions for the Fraudulent Pharmaceuticals are always filled by 21st Century, even in the rare instance when the prescription is not submitted on a Fraudulent Script generated by 21st Century itself.

118. Indeed, on those occasions when one of 21st Century’s Fraudulent Scripts is not used, the Prescribing Defendants’ scripts, rather than containing a handwritten, individualized prescription, often use a pre-printed label or a stamp that designates on the prescription form what pre-determined and mass produced Compounded Product is being prescribed.

(iii) The Insufficient Initial Evaluation and Re-Evaluation Reports

119. In basic terms, the goal of medical treatment is to help patients get better in a timely manner. Notwithstanding this basic goal, the Insureds treated by the Prescribing Defendants are virtually always subjected to a predetermined treatment protocol, which is both unnecessarily prolonged and totally lacking in individualized care, which does not utilize evidence based practices with the goal of the Insureds timely return to good health. Conversely, the treatment reports almost uniformly reflect that the Insureds treated by the Prescribing Defendants do not get better, do not return to good health, and/or do not experience improvement in their conditions such that the Insureds can terminate medical treatment expeditiously and return to normal activity.

120. As part of the pre-determined protocol, the Prescribing Defendants produce evaluation reports that are generic, preprinted, and boilerplate, designed to justify continuing, voluminous and excessive healthcare services that the No-Fault Clinic providers purport to render to Insureds thereafter – including the prescription of Fraudulent Pharmaceuticals.

121. Notwithstanding the creation of evaluation reports, the Prescribing Defendants' prescriptions of the Fraudulent Pharmaceuticals are not medically necessary and based on a pre-determined treatment and billing protocol, provided without regard to the genuine needs of the patients.

122. To the extent any evaluation is performed at all, the Prescribing Defendants fail to document a detailed medical history of the patients to whom they prescribe the Fraudulent Pharmaceuticals. Prescribing Compounded Products without first taking a detailed patient history demonstrates a gross indifference to patient health and safety as the Prescribing Defendants do not know whether the patient is currently taking any medication or suffering from any co-morbidities that would contraindicate the use of a Compounded Product. It is also indicative that the Prescribing Defendants did not prescribe the Compounded Products to meet the unique needs of a particular patient that could not be met with an existing FDA approved medication because the inadequate examinations would not be able to identify any such unique needs.

123. Moreover, most of the Prescribing Defendants' initial evaluation reports and re-evaluation reports make no mention whatsoever of the various Fraudulent Pharmaceuticals the Insureds have been prescribed.

124. To the extent the initial evaluation reports do reference any medications (i) they fail to reference all of the Fraudulent Pharmaceuticals allegedly prescribed; (ii) they reference medications other than the Fraudulent Pharmaceuticals actually prescribed; (iii) they refer to the

prescribed medications through non-specific, preprinted, boilerplate language such as “Rx: Patient explained in details [sic] how to take prescribed medications” or “pain lotion” without indicating which specific medication(s) and/or Compounded Products were prescribed or what injuries or symptoms the prescribed medication(s) are intended to treat.

125. In many instances, the initial evaluation report of the Prescribing Defendants document the prescription of a *different* drug than that actually prescribed, and ultimately dispensed and billed by 21st Century. For example:

<u>Claimant</u>	<u>Claim Number</u>	<u>Prescription Drug Documented in Initial Evaluation</u>	<u>Prescription Drug Dispensed and Billed</u>	<u>Prescribing Physician Defendant</u>
L.M.	066572690101058	Diclofenac Gel 3%; Terocin Patches	GP1 ² ; Terocin Patches	Duhamel
C.A.	0227185570101069	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
G.M.	0235112440101012	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
M.R.	0272640030101103	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
J.M.	0396539210101019	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
M.Z.	0404649550101022	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
V.A.	0416754450101027	None	GP1; Terocin Patches	Duhamel
C.P.	0423212340101039	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
A.C.	0455426620101060	Diclofenac Gel	GP1; Terocin Patches	Duhamel
C. J.	0455426610101060	Diclofenac Gel	GP1; Terocin Patches	Duhamel
I.C.	0459572810101026	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
L.C.	0462582720101037	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
R.G.	0473349660101113	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
W.A.	0481313810101043	Diclofenac Gel 3%;	GP1; Terocin	Duhamel

² According to 21st Century’s pre-printed prescription forms, “GP1 Musculoskeletal Pain” is a General Pain Lotion containing Baclofen 4%, Tetracaine 2%, Ketorolac 5%, Diclofenac 3% and Verapamil 6%.

<u>Claimant</u>	<u>Claim Number</u>	<u>Prescription Drug Documented in Initial Evaluation</u>	<u>Prescription Drug Dispensed and Billed</u>	<u>Prescribing Physician Defendant</u>
		Terocin Patches	Patches	
D.L.	0481313810101043	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
M.R.	0485723110101020	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
A.S.	0493902190101023	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
D.A.	0493902190101023	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
K.G.	0498068920101025	Diclofenac Gel	GP1; Terocin Patches	Duhamel
D.S.	0506618150101028	Diclofenac Gel	GP1; Terocin Patches	Duhamel
A.C.	0524685170101013	Diclofenac Gel	GP1; Terocin Patches	Duhamel
A.M.	0527121770101010	None	Diclofenac Gel 3%	Duhamel
D.C.	0530979770101016	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
D.C.	0536648770101011	Diclofenac Gel 3%; Terocin Patches	GP1; Terocin Patches	Duhamel
B.W.	0338673220101056	Naproxen; Flexural	NP3; Terocin Patches	Howell
P.S.	0636095200101039	Naproxen; Flexural	NP3; Terocin Patches	Howell
S.L.	0429855370101065	Naproxen; Flexural	NP3; Terocin Patches	Howell
M.A.	0434146190101037	Naproxen; Flexural	NP3; Terocin Patches	Howell
H.D.	0446785990101022	Naproxen; Flexural	NP3; Terocin Patches	Howell
S.S.	0446785990101022	Naproxen; Flexural	NP3; Terocin Patches	Howell
K.C.	0446917420101021	Naproxen; Flexural	NP3; Terocin Patches	Howell
J.O.	0446917420101021	Naproxen; Flexural	NP3; Terocin Patches	Howell
N.G.	0449434730101029	Naproxen; Tylenol	NP3; Terocin Patches	Howell
J.T.	0449434730101029	Naproxen; Flexural	Np3; Terocin Patches	Howell
S.J.	0469709560101024	Naproxen; Flexural	NP3; Terocin Patches	Howell
F.D.	0528992070101010	Naproxen; Flexural	Terocin Patches	Howell
V.S.	0087653840101218	"Pain Lotion"	GP1	Sheikh

<u>Claimant</u>	<u>Claim Number</u>	<u>Prescription Drug Documented in Initial Evaluation</u>	<u>Prescription Drug Dispensed and Billed</u>	<u>Prescribing Physician Defendant</u>
D.O.	0091338640101147	Ibuprofen	GP6	Sheikh
M.M.	0132340820101070	"Pain Lotion"	GP6	Sheikh
K.S.	0179718140101066	"Pain Lotion"	GP6	Sheikh
E.C.	0180454520101024	"Pain Lotion"	GP6	Sheikh
D.V.	0216827880101031	Tylenol; "pain lotion"	GP6	Sheikh
D.T.	0274795880101039	"Pain Lotion"	GP1	Sheikh
J.R.	0295832510101108	"Pain Lotion"	GP1	Sheikh
D.K.	0319074870101046	None	GP6	Sheikh
S.C.	0332594170101068	"Pain Lotion"	GP6	Sheikh
L.N.	0332594170101068	"Pain Lotion"	GP6	Sheikh
S.H.	0399013620101081	"Pain Lotion"	GP6	Sheikh
A.G.	0418743000101049	Naproxen; "pain lotion"	GP6	Sheikh
T.Z.	0419279580101041	Ibuprofen and "Pain Lotion"	GP6	Sheikh
I.H.	0421131540101064	"Pain Lotion"	GP1	Sheikh
O.R.	0425948830101017	"Pain Lotion"	GP1	Sheikh
N.S.	0425948830101017	"Pain Lotion"	GP6	Sheikh
C.R.	0443514380101019	Naproxen; Voltaren Gel; "pain lotion"	GP6	Sheikh
H.B.	0532346740101013	"Pain Lotion"	GP6	Sheikh
T.E.	0521116180101010	Voltaren Gel / "pain cream"	NP3	Dovlatyan
E.B.	0526595760101018	Flexural; Ibuprofen	GP4	Dovlatyan
T.W.	0529514090101017	None	GP4	Dovlatyan
P.L.	0092038090101196	None	GP6	Dovlatyan
R.Y.	0100321370101072	Voltaren Gel; Percocet; Flexural	GP8	Dovlatyan
E.R.	0101227010101084	"Pain Compound"	GP4 and GP8 (prescribed on same date)	Dovlatyan
S.H.	0114029000101065	None	GP8	Dovlatyan
V.R.	0134871460101200	None	NP3 and GP1 (prescribed three days apart)	Dovlatyan
S.B.	0243700480101015	Voltaren Gel / "pain cream"	GP8	Dovlatyan
A.G.	0508357740101010	None	NP3	Dovlatyan
G.M.	0508357740101010	None	GP7	Dovlatyan
J.F.	0536640230101012	None	Naproxen; Flexural; Terocin Patches; Diclofenac Gel 3%	Ajudua

<u>Claimant</u>	<u>Claim Number</u>	<u>Prescription Drug Documented in Initial Evaluation</u>	<u>Prescription Drug Dispensed and Billed</u>	<u>Prescribing Physician Defendant</u>
M.T.	0536009150101016	None	Ibuprofen; Cyclobenzaprine ; Terocin Patches; Diclofenac Gel 3%	Ajudua
R.N.	0533056330101013	None	Ibuprofen; Cyclobenzaprine ; Terocin Patches; Diclofenac Gel 3%	Ajudua
D.O.	0499311150101029	None	Naproxen; Terocin Patches; Diclofenac Gel 3%	Ajudua
B.N.	0538662530101011	None	Naproxen; Terocin Patches; Diclofenac Gel 3%	Ajudua
J.B.	0534234510101017	None	Naproxen; Terocin Patches	Ajudua
S.M.	0534234510101017	None	Naproxen; Nexium; Terocin Patches	Ajudua
F.D.	0512384890101016	None	Naproxen; Terocin Patches; Diclofenac Gel 3%	Ajudua
D.C.	0501447950101037	None	Ibuprofen; Cyclobenzaprine ; Terocin Patches; Diclofenac Gel 3%	Ajudua
M.S.	0493684960101017	None	Cyclobenzaprine ; Duexis; Diclofenac Gel 3%; Terocin Patches	Ajudua
M.T.	0496142530101014	None	GP2; Terocin Patches	Ajudua

126. The numerous inconsistencies between the Prescribing Defendants' evaluation reports and the drugs actually dispensed again evidences that (i) the Fraudulent Pharmaceuticals

are not medically necessary and are provided and billed for pursuant to a pre-determined fraudulent billing and treatment protocol; (ii) the Compounded Products are not individually tailored to meet the unique needs of a particular patient in response to a valid prescription and, therefore, not FDA exempt; (iii) the Pharmacy Defendants and the Prescribing Defendants are engaged in collusive kickback arrangements; and (iv) 21st Century is not a neighborhood pharmacy, but a large scale manufacturer and producer of pre-determined, mass produced drug products acting in violation of law.

127. Also notable, in many cases, each Prescribing Defendant documents the same particular drug to be prescribed for each of its patients, and 21st Century dispenses and bills for the same Fraudulent Pharmaceuticals for each of that Prescribing Defendant's patients. For example, Duhamel continuously documents Diclofenac Gel 3% and Terocin to be prescribed, yet 21st Century always bills for and dispenses its GP1 Compounded Product to Duhamel's patients despite the fact that it does dispense and bill for non-compounded Diclofenac Gel 3% for other Insureds not treated by Duhamel. Comparatively, Howell continuously documents Naproxen and Flexural to be prescribed, yet 21st Century continuously bills for and dispenses its NP3 Compounded Product for Howell's patients.

128. Moreover, the Prescribing Defendants' re-evaluation reports rarely make any reference to the Fraudulent Pharmaceuticals previously prescribed to the patients. If the report does reference the fact that the patient was previously prescribed one of the Fraudulent Pharmaceuticals, it does so with boilerplate language such as "continue with pain lotion" or "continue with analgesics." The re-evaluation reports do not indicate which specific Fraudulent Pharmaceutical the patient was previously prescribed nor do they indicate what, if any, therapeutic benefits or side effects the patient reported from using the Fraudulent Pharmaceuticals.

(iv) **The Defendants' Mislabeling of the Compounded Products**

129. Pursuant to New York Education Law § 6815(2)(j), labels for compounded drugs:

“shall ... contain[] ... directions for use as may be stated in the prescription, ... name of the physician or other practitioner authorized by law to issue the prescription. In addition, such label shall contain the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.”

130. 21st Century's labels (i) do not contain any directions for use; (ii) fail to list the proprietary or brand name of the drug and instead just state “Compound”; and (iii) fail to state the strength of the contents.

131. 21st Century's failure to comply with the licensing requirements regarding the proper labelling of drugs is so egregious that in many instances the name of the physician is incorrect. Indeed, for every prescription of Fraudulent Pharmaceuticals purportedly written by Defendant Sheikh (many of which list an incorrect National Provider Identifier (“NPI”) number or lack a prescriber name), the corresponding labels generated by 21st Century and submitted with the bills indicate the wrong physician as the prescribing healthcare provider.

C. **The Prescription and Dispensation of 21st Century's Compounded Products is Contrary to Evidenced-Based Medical Practices**

132. In keeping with the fact that the Fraudulent Pharmaceuticals are prescribed pursuant to the Defendants' fraudulent scheme intended to generate profits from insurers, 21st Century's Compounded Products (i) have no medical efficacy based on the purported symptoms of the patients receiving the Compounded Products; (ii) are prescribed and administered repeatedly as first line therapy contrary to evidenced-based medical practices; and (iii) are prescribed without any legitimate reason to provide the patients with expensive Compounded Products – which include drugs whose efficacy in topical form is undocumented and

unsupported – when there are many other widely accepted, proven effective alternatives with well documented therapeutic benefits commercially available at considerably lower costs.

133. Evidence-based guidelines for the treatment of acute pain do exist and should always guide prescribing habits. The World Health Organization (“WHO”) pain relief ladder recommends a non-opioid such as acetaminophen or a nonsteroidal anti-inflammatory drug (NSAID) for the initial management of pain. NSAIDs are the most commonly prescribed analgesic medications worldwide, and their efficacy for treating acute pain has been well demonstrated. If pain relief is not achieved, then an adjuvant oral agent may be added to the medication regimen – including the use of muscle relaxers, and medications that block neuropathic pain transmission. Finally, opiates may be prescribed for short-term, limited use. Clinical studies of FDA-approved topical NSAIDs have shown them to be no more effective than placebo for treating acute pain (e.g., from strains, sprains, contusions, or overuse injuries) in superficial locations.

134. Because Compounded Products are not FDA approved – and therefore not subject to FDA regulations regarding quality, safety and effectiveness of manufactured drug products – they should never be prescribed as routine therapy, and should only be prescribed to meet a legitimate specific need of an individual patient, or when all other forms of oral and/or topical medications approved for the treatment of pain have failed.

135. Topical compounded creams should be the last prescribed intervention after oral medications are not tolerated or are deemed ineffective as well as any FDA-approved manufactured topical products have also been shown to provide no pain relief to the patient.

136. For a topical formulation to be effective, it must first penetrate the skin. In general, creams are less effective than gels or sprays.

137. The skin is composed of three layers: epidermis, dermis, and hypodermis. Within

the epidermis, the stratus corneum is the outermost layer of the skin that serves as the main barrier to drug entry. For analgesic medicines to be absorbed through the skin, they must contain optimal drug combinations, effective concentrations of each drug, and a compounding base with the appropriate physiochemical properties to facilitate absorption.

138. In order for a drug to alleviate pain, it must reach nerve or tissue receptors responsible for producing or transmitting a person's sensation of pain.

139. Oral pain relievers reduce or alleviate pain by entering the bloodstream through the gastrointestinal system and traveling to the relevant nerve or tissue receptors. Some of the limited circumstances in which a physician would prescribe a topical medication include patients in whom these oral medications are contraindicated – those with moderate to severe kidney or liver dysfunction, or those with comorbidities that preclude the use of oral nonsteroidal anti-inflammatory drugs (e.g., history of peptic ulcer disease or congestive heart failure).

140. 21st Century's Compounded Products contain combinations of drugs that make no clinical sense and have no efficacious value in treating musculoskeletal and neuropathic injuries – assuming the Insureds the Defendants treat suffer from such injuries.

141. There are no published, peer-reviewed, controlled studies to support that patients who suffer from musculoskeletal pain or neuropathy have achieved any therapeutic effect from using topical creams containing the drugs that are part of 21st Century's Compounded Products.

142. Further, many of 21st Century's Fraudulent Pharmaceuticals are available in oral formulations or are commercially available in different topical formulations. These alternatives are proven to therapeutically benefit patients with musculoskeletal and neuropathic pain, are FDA approved, and are commonly recommended and prescribed among healthcare providers who utilize evidence-based medicine for their prescribing practices.

143. The Prescribing Defendants, however, do not prescribe, and the Pharmacy Defendants never dispense, any non-compounded, manufactured prescription topical medications prior to prescribing the Compounded Products.

144. Contrary to evidenced-based medical practices, 21st Century's Compounded Products are prescribed and administered repeatedly as first line therapy.

145. The fact that the Defendants prescribe non-FDA approved medications upon first consultation with a patient – medications that have no proven efficacy in the medical literature but entail exorbitant cost – is further indicative that the Defendants are not practicing evidence-based medicine and prescribe the Compounded Products pursuant to a fraudulent pre-determined treatment and billing protocol designed to enrich the Defendants.

146. Finally, the combination of drugs used in 21st Century's Compounded Products is merely another means for the Defendants to maximize their billing and exploit New York automobile insurance carriers as 21st Century is statutorily reimbursed for each individual ingredient contained in the Compounded Products.

147. The Defendants' scheme involving Compounded Drugs poses substantial risks to patient care and safety. For example, a published case report of a 23-year-old man prescribed topical clonidine/gabapentin/imipramine/ketamine/lidocaine/mefenamic acid in a prepared compounded cream describes admission to a hospital intensive care unit requiring intubation; the patient was found to have elevated clonidine blood concentrations indicating drug toxicity.

D. The Fraudulent Pain Patches

148. In addition to engaging in large-scale drug manufacturing under the guise of pharmacy compounding, the Prescribing Defendants purport to prescribe various Pain Patches – including Terocin Patches, Lidoderm Patches and Flector Patches – by means of the Fraudulent Scripts.

149. In keeping with the fact that the Fraudulent Pharmaceuticals are prescribed pursuant to pre-determined treatment and billing protocols designed to maximize profits without regard to patient care, the Defendants prescribe, dispense and bill for non-proprietary Pain Patches at exorbitant prices despite the fact that there are other, less expensive, commercially available FDA approved patches available.

150. For example, 21st Century dispenses and bills for Terocin 4% patches – a non-prescription item – at \$2,556.00 for a box of sixty (60). Not only are Terocin Patches available for purchase for nearly half the price, but in addition to menthol, the primary ingredient in Terocin Patches is Lidocaine which itself is available in an FDA approved patch for a fraction of the cost.

151. As with the Compounded Products, many patients are not aware they are to receive any Pain Patches until the patches are given to them by the receptionists at the No-Fault Clinics or are mailed to the patients' homes.

152. In keeping with the fact that the Defendants act with gross indifference to patient care and safety, the patients are generally not instructed on the safe use, side effects or risks associated with the Pain Patches which may include blood toxicity and symptoms of overdose if not used correctly.

II. The Fraudulent Billing the Defendants Submitted or Caused to be Submitted to GEICO

A. The Regulations Governing the Maximum Reimbursement of Pharmaceutical Products and the Defendants' Fraudulent Billing

153. The maximum amount that a healthcare provider may charge for a medically necessary Compounded Product is based on each individual ingredient included in the Compounded Product. Each prescribed ingredient, whether a brand name or generic drug, included in a Compounded Product has a designated national drug code ("NDC") – a unique 10-

digit code that identifies the drug itself, the vendor of the drug and the quantity in which the drug was packaged. Each NDC number has an assigned Average Wholesale Price (“AWP”).

154. Each NDC (and, thus, the AWP) for a particular ingredient differs depending on both the particular supplier the drug is purchased from and the quantity in which the drug is obtained. The same drug can have a different NDC number if it is purchased from a different supplier and/or in different quantities.

155. Pursuant to 12 N.Y.C.R.R. §§ 440.5(a) and (d) (the “Pharmacy Fee schedule”), for each brand name drug included in a Compounded Product, a provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 12% of the AWP, plus a single dispensing fee of \$4.00.

156. For each generic drug included in a Compounded Product, the provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 20% of the AWP, plus a single dispensing fee of \$5.00.

157. AWP is defined by 12 N.Y.C.R.R. § 440.2(a) as:

“[t]he average wholesale price of a prescription drug as provided in the most current release of the Red Book published by Thomson Reuters or Medi-Span Master Drug Database by Wolters Kluwer Health or any successor publisher, on the day a prescription drug is dispensed or other nationally recognized drug pricing index adopted by the Chair or Chair's designee.”

158. When a pharmacist bills for dispensing Compounded Products, it must bill based on the actual NDC number (and the assigned AWP) of each of the ingredients dispensed as part of the Compounded Product. It cannot use the NDC of the same ingredient available from a different supplier and/or purchased in different quantities in order to inflate the assigned AWP.

B. 21st Century’s Fraudulent Charges

159. 21st Century purports to provide the Fraudulent Pharmaceuticals directly to GEICO Insureds and seeks reimbursement directly from GEICO pursuant to prematurely

executed AOBs. With regard to Compounded Products, 21st Century's bills list each ingredient separately along with the corresponding charge for each. The total billed amount for 21st Century's Compounded Products varies from approximately \$500.00 to in excess of \$6,400.00 per dosage.

160. In support of its charges, 21st Century submits (i) the invalid Fraudulent Script or other formulaic script purportedly signed by one of the Prescribing Defendants – if signed at all; (ii) a HCFA-1500 Form which includes the purported NDC numbers, units and corresponding charges for each ingredient in the billed-for Compounded Product; (iii) an NF-3 Form; (iv) an invoice sent directly to the patient listing the total amount due as well as finance charges that will be applied if the invoice is not promptly paid; and (v) a delivery slip and/or Federal Express signature confirmation page.

161. The NDC numbers listed on the HCFA-1500 Forms submitted by 21st Century identify the various alleged sources from which 21st Century obtains the ingredients for its Compounded Products and the alleged AWP's for such products.

162. Notably, 21st Century never submits its purchase invoices demonstrating how much 21st Century paid the supplier for the ingredients or the quantities in which the ingredients were obtained.

163. A review of 21st Century's billing reveals that it charges for its Compounded Products without any regard to the Pharmacy Fee Schedule.

164. Specifically, pursuant to the provisions of the Pharmacy Fee Schedule governing Compounded Products, 21st Century is entitled to the AWP minus 12% (for brand name drugs) or 20% (for generic name drugs) for each ingredient in the Compounded Product.

165. Yet 21st Century routinely bills GEICO pursuant to the AWP's without applying any reduction whatsoever as required by the Pharmacy Fee Schedule.

166. Even more egregiously, 21st Century has submitted billing for reimbursement of Compounded Products at a rate that exceeds the actual AWP for the supplier 21st Century purported to obtain its ingredients from.

167. For example Claimant T.B. (Claim No. 0105650560101186) was allegedly provided with 21st Century's Compounded Product "NP3. Back Pain" which contains Gabapentin, Clonidine, Diclofenac, Lidocaine, Pentoxifylline and Versapro cream base. The documents the Defendants submitted in support of 21st Century's charges, specifically the NDCs listed therein, indicate 21st Century obtained the ingredients from Medisca, a provider of compounding products and supplies. The chart below represents the ingredients, units, billed amount and AWP for each ingredient in the Compounded Product prescribed to Claimant T.B.

Ingredient	Units	Billed Amount	Medisca AWP
Gabapentin	18 g	1077.20	897.75
Clonidine	.3 g	61.84	61.98
Diclofenac	6 g	88.82	88.74
Lidocaine HCl	6.0 g	25.66	25.64
Pentoxifylline	15 g	124.34	124.20
Versapro Cr	254.70 g	815.14	815.04
Totals		\$2,193.00	\$2,013.35

168. Defendants, through 21st Century, submitted a bill to GEICO totaling \$2,193.00. Even assuming that 21st Century's documents reflect legitimate NDCs and corresponding AWP and that these figures are not fraudulent, it would still only be entitled to receive \$1,929.84 (\$2,193.00 – 12%) for the "NP3. Back Pain" Compounded Product administered to T.B. – a difference of \$263.39.

169. However, as the chart reflects, 21st Century's total billed amount is more than the total AWP for Medisca's ingredients which is \$2,013.35. Based on Medisca's AWP total, 21st Century would be entitled to no more than \$1,771.75 ($\$2,013.35 - 12\%$) – over \$400.00 less than what 21st Century actually charged.

170. Defendants, through 21st Century, also charge above and beyond that to which they are entitled under the Pharmacy Fee Schedule for Pain Patches. For example, Claimant T.Y. (Claim No. 0145208560101045) was allegedly provided with sixty (60) Lidoderm Patches for which the Defendants billed GEICO \$1,071.64. Based on the AWP of this product, 21st Century would be entitled to no more than \$754.35 (AWP of \$857.26 – 12%) – over \$300.00 less than what 21st Century actually charged.

171. Claimant S.O. (Claim No. 0109567980101123) was allegedly provided with thirty (30) Flector Patches for which the Defendants billed GEICO \$439.74. Based on the AWP of this product, 21st Century would be entitled to no more than \$396.16 (AWP of \$347.92 – 12%) – a \$40.00 difference.

172. While these may not appear to be exorbitant overcharges on a single claim basis, considering the Defendants have billed GEICO for Fraudulent Pharmaceuticals prescribed and allegedly dispensed to thousands of Insureds, the fraudulent charges exceed millions of dollars submitted to GEICO alone.

173. These figures do not account for fraudulent charges that may be submitted to carriers other than GEICO.

III. The Defendants' Submission of Fraudulent NF-3 Forms to GEICO

174. To support the fraudulent charges, statutorily prescribed claim forms for No-Fault Benefits consistently have been submitted to GEICO by and on behalf of 21st Century seeking payment for the pharmaceuticals for which it is ineligible to received payment.

175. The NF-3 forms, HCFA-1500 forms and other supporting records that the Defendants submitted or caused to be submitted to GEICO were false and misleading in the following material respects:

- (i) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Pharmacy Defendants complied with all material licensing laws and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Pharmacy Defendants did not comply with all material licensing laws in that they engaged in illegal compounding by producing and dispensing vast quantities of the Compounded Products in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities.
- (ii) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Pharmacy Defendants complied with all material licensing laws and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Pharmacy Defendants did not comply with all material licensing laws in that they paid kickbacks and entered into collusive arrangements with the Prescribing Defendants and other prescribing physicians for patient referrals.
- (iii) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Fraudulent Pharmaceuticals were medically necessary. In fact, the Fraudulent Pharmaceuticals were not medically necessary and were provided – to the extent that they were provided at all – pursuant to a pre-determined fraudulent treatment and billing protocol designed solely to financially enrich the Defendants, rather than to treat or otherwise benefit the Insureds who purportedly were provided with them.
- (iv) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to GEICO that the Fraudulent Pharmaceuticals were prescribed pursuant to valid prescriptions. In fact, the Fraudulent Pharmaceuticals were not provided pursuant to valid prescriptions, rather

the Fraudulent Scripts were pre-determined, formulaic and/or in violation of N.Y. Public Health Law § 281, N.Y. Education Law § 6810(6)(a), N.Y. Education Law § 6810(7) and N.Y. Education Law § 6810(8).

- (v) The NF-3 forms, HCFA-1500 forms, and other supporting documents uniformly misrepresented to GEICO that the Fraudulent Pharmaceuticals were billed properly and in accordance with the maximum permissible charges. In fact, the Pharmacy Defendants misrepresented and exaggerated the proper charges for the Fraudulent Pharmaceuticals.

IV. The Defendants' Fraudulent Concealment and GEICO's Justifiable Reliance

176. The Defendants are legally and ethically obligated to act honestly and with integrity in connection with the provision of pharmaceutical products to Insureds and the billing they submit or cause to be submitted to GEICO seeking reimbursement for these products.

177. To induce GEICO to promptly pay the charges for the Fraudulent Pharmaceuticals, the Defendants have gone to great lengths to systematically conceal their fraud.

178. Specifically, the Defendants knowingly have misrepresented and concealed facts in an effort to prevent discovery that the Defendants (i) are in violation of licensing laws governing manufacturers and large-scale drug outsourcing facilities of Compounded Drugs; (ii) are involved in collusive, kickback arrangements to generate voluminous prescriptions pursuant to a fraudulent pre-determined treatment and billing protocol, without regard to genuine patient care; (iii) use Fraudulent Scripts and other formulaic scripts that are predetermined and/or invalid under New York Public Health Law and New York Education Law; (iv) prescribe and dispense Fraudulent Pharmaceuticals that have no efficacious value and grossly exceed the cost of effective FDA approved medications; and (v) routinely seek reimbursement above that to which they may be entitled under the Pharmacy Fee Schedule.

179. GEICO maintains standard office practices and procedures that are designed to and do ensure that No-Fault claim denial forms or requests for additional verification of No-Fault

claims are properly addressed and mailed in a timely manner in accordance with the No-Fault Laws.

180. In accordance with the No-Fault Laws, and GEICO's standard office practices and procedures, GEICO either: (i) timely denied the pending claims for No-Fault Benefits submitted through 21st Century; (ii) timely issued requests for additional verification with respect to the pending claims for No-Fault Benefits submitted through 21st Century, yet failed to obtain complete compliance with the requests for additional verification; or else (iii) the time in which to deny the pending claims for No-Fault Benefits submitted through 21st Century, or to request additional verification of those claims, has not yet expired.

181. The Defendants have hired law firms to pursue collection of the fraudulent charges from GEICO and other insurers. These law firms routinely file expensive and time-consuming litigation against GEICO and other insurers if the charges are not promptly paid in full. In fact, 21st Century continues to have legal counsel pursue collection against GEICO and other insurers without regard for the fact that 21st Century has been engaged in fraud.

182. GEICO is under statutory and contractual obligations to promptly and fairly process claims within 30 days. The facially-valid documents that were submitted to GEICO in support of the fraudulent charges at issue, combined with the material misrepresentations described above, were designed to and did cause GEICO to rely upon them. As a result, GEICO has incurred damages of approximately \$2,559,000.00 representing payments made by GEICO based upon the fraudulent charges submitted by the Defendants.

183. Based upon the Defendants' material misrepresentations and other affirmative acts to conceal their fraud from GEICO, GEICO did not discover and could not reasonably have discovered that its damages were attributable to fraud until shortly before it filed this Complaint.

AS AND FOR THE FIRST CAUSE OF ACTION
Against All Defendants
(Declaratory Judgment – 28 U.S.C. §§ 2201 and 2202)

184. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

185. There is an actual case in controversy between GEICO and the Defendants regarding approximately \$6,211,000.00 in fraudulent billing for the Fraudulent Pharmaceuticals that has been submitted to GEICO.

186. Defendants have no right to receive payment for any pending bills submitted to GEICO because:

- (i) 21st Century engaged in illegal compounding by producing and dispensing vast quantities of the Compounded Products in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault benefits;
- (ii) the Pharmacy Defendants participated in illegal collusive relationships with various physicians, including the Prescribing Defendants, who prescribed the medically unnecessary Fraudulent Pharmaceuticals in exchange for unlawful kickbacks and other financial considerations;
- (iii) the Defendants made false and fraudulent misrepresentations to GEICO in that the Fraudulent Pharmaceuticals were not medically necessary and were provided – to the extent they were provided at all – pursuant to pre-determined fraudulent treatment and billing protocols designed solely to financially enrich the Defendants, rather than to treat or otherwise benefit the Insureds who purportedly received them;
- (iv) the Defendants made false and fraudulent misrepresentations to GEICO concerning the maximum permissible charges for the Fraudulent Pharmaceuticals allegedly provided to Insureds in order to induce GEICO to reimburse 21st Century for No-Fault Benefits to which it is not entitled; and
- (v) the Defendants made false and fraudulent misrepresentations to GEICO by submitting or causing to be submitted charges for Fraudulent Pharmaceuticals pursuant to invalid, duplicitous and formulaic prescriptions.

187. Accordingly, GEICO requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, declaring that Defendants have no right to receive payment for any pending bills submitted to GEICO.

AS AND FOR THE SECOND CAUSE OF ACTION

**Against Alishayev
(Violation of RICO, 18 U.S.C. § 1962(c))**

188. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

189. 21st Century is an ongoing “enterprise”, as that term is defined in 18 U.S.C. § 1961(4), that engages in activities which affect interstate commerce.

190. Alishayev knowingly has conducted and/or participated, directly or indirectly, in the conduct of 21st Century’s affairs through a pattern of racketeering activity consisting of repeated violations of the federal mail fraud statute, 18 U.S.C. § 1341, based upon the use of the United States mails to submit or cause to be submitted hundreds of fraudulent charges on a continuous basis for over two years seeking payments that 21st Century was not eligible to receive under the No-Fault Laws because: (i) it engaged in illegal compounding and manufactured, produced, and dispensed vast quantities of the Compounded Products in set formulations, in violation of Federal and New York State regulatory and licensing requirements; (ii) it engaged in unlawful kickback arrangements with licensed physicians; (iii) the billed-for-services were not medically necessary; (iv) the billed-for-services were performed and billed pursuant to a pre-determined, fraudulent treatment and billing protocol designed solely to enrich the Defendants; (v) the Defendants made false and fraudulent misrepresentations to GEICO concerning the maximum permissible charges for the services that purportedly were provided in

order to inflate the charges that could be submitted; and (vi) the billed-for-services were provided pursuant to invalid and/or duplicitous prescriptions.

191. 21st Century's business is racketeering activity, inasmuch as the enterprise exists for the purpose of submitting fraudulent charges to insurers. The predicate acts of mail fraud are the regular way in which Alishayev operated 21st Century, inasmuch as 21st Century never was eligible to bill for or collect No-Fault Benefits, and acts of mail fraud therefore were essential in order for 21st Century to function. Furthermore, the intricate planning required to carry out and conceal the predicate acts of mail fraud implies a threat of continued criminal activity, as does the fact that the Defendants continue to attempt collection on the fraudulent billing submitted through 21st Century to the present day.

192. 21st Century is engaged in inherently unlawful acts inasmuch as its very existence is an unlawful act, considering that it was created to engage in kickbacks and render services pursuant to fraudulent, invalid prescriptions. 21st Century likewise is engaged in inherently unlawful acts inasmuch as it continues to attempt collection on fraudulent billing submitted to GEICO and other insurers. These inherently unlawful acts are taken by 21st Century in pursuit of inherently unlawful goals – namely, the theft of money from GEICO and other insurers through fraudulent No-Fault billing.

193. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately \$2,559,000.00 pursuant to the fraudulent bills submitted by the Defendants through 21st Century.

194. By reason of its injury, GEICO is entitled to treble damages, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c), and any other relief the Court deems just and proper.

AS AND FOR THE THIRD CAUSE OF ACTION
Against Alishayev and the Prescribing Defendants
(Violation of RICO, 18 U.S.C. § 1962(d))

195. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

196. 21st Century is an ongoing “enterprise”, as that term is defined in 18 U.S.C. § 1961(4), that engages in activities which affect interstate commerce.

197. Alishayev and the Prescribing Defendants are employed by and/or associated with the 21st Century enterprise.

198. Alishayev and the Prescribing Defendants knowingly have agreed, combined and conspired to conduct and/or participate, directly or indirectly, in the conduct of 21st Century enterprise’s affairs, through a pattern of racketeering activity consisting of repeated violations of the federal mail fraud statute, 18 U.S.C. § 1341, based upon the use of the United States mails to submit or cause to be submitted hundreds of fraudulent charges on a continuous basis for over two years seeking payments that 21st Century was not eligible to receive under the No-Fault Laws because: (i) it engaged in illegal compounding and manufactured, produced, and dispensed vast quantities of the Compounded Products in set formulations, in violation of Federal and New York State regulatory and licensing requirements; (ii) it engaged in unlawful kickback arrangements with licensed physicians; (iii) the billed-for-services were not medically necessary; (iv) the billed-for-services were performed and billed pursuant to a pre-determined, fraudulent treatment and billing protocol designed solely to enrich the Defendants; (v) the Defendants made false and fraudulent misrepresentations to GEICO concerning the maximum permissible charges for the services that purportedly were provided in order to inflate the charges that could be submitted; and (vi) the billed-for-services were provided pursuant to invalid and/or duplicitous prescriptions.

199. Alishayev and the Prescribing Defendants knew of, agreed to and acted in furtherance of the common and overall objective (i.e., to defraud GEICO and other insurers of money) by submitting or facilitating the submission of the fraudulent charges to GEICO.

200. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately \$2,559,000.00 pursuant to the fraudulent bills submitted by the Defendants through 21st Century.

201. By reason of its injury, GEICO is entitled to treble damages, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c), and any other relief the Court deems just and proper.

AS AND FOR THE FOURTH CAUSE OF ACTION
Against All Defendants
(Common Law Fraud)

202. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

203. The Pharmacy Defendants and the Prescribing Defendants intentionally and knowingly made false and fraudulent statements of material fact to GEICO and concealed material facts from GEICO in the course of their submission of thousands of fraudulent bills seeking payment for the Fraudulent Pharmaceuticals.

204. The false and fraudulent statements of material fact and acts of fraudulent concealment include: (i) in every claim, the representation that 21st Century was properly licensed, and therefore, eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact it engaged in illegal compounding and manufactured, produced, and dispensed large volumes of compound drug products in set formulations in violation of New York and Federal law; (ii) in every claim, the representation that 21st Century was properly licensed and, therefore, eligible to receive No-Fault Benefits

pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact it engaged in kickback arrangements with licensed physicians in violation of New York law; (iii) in every claim, the representation that the billed-for services were medically necessary and properly billed in accordance with the Pharmacy Fee Schedule, when in fact the billed-for services were not medically necessary and were billed pursuant to a pre-determined, fraudulent treatment and billing protocol designed solely to enrich the Defendants; (iv) in every claim, the representation that the billed-for-services were provided pursuant to legitimate prescriptions, when in fact the billed-for-services were provided pursuant to fraudulent prescriptions in violation of New York law; and (v) in every claim, the representation that the billed-for-services were properly and legitimately charged in response to legitimate prescriptions, when in fact, the charges were both unnecessary and inflated.

205. The Pharmacy Defendants and Prescribing Defendants intentionally made the above-described false and fraudulent statements and concealed material facts in a calculated effort to induce GEICO to pay charges submitted through 21st Century that were not compensable under the No-Fault Laws.

206. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately \$2,559,000.00 pursuant to the fraudulent bills submitted, or caused to be submitted, by the Defendants through 21st Century.

207. The Defendants' extensive fraudulent conduct demonstrates a high degree of moral turpitude and wanton dishonesty that entitles GEICO to recover punitive damages.

208. Accordingly, by virtue of the foregoing, GEICO is entitled to compensatory and punitive damages, together with interest and costs, and any other relief the Court deems just and proper.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST
Against the Prescribing Defendants
(Aiding and Abetting Fraud)

209. GEICO incorporates, as though fully set forth herein, each and every allegation set forth above.

210. The Prescribing Defendants (*i.e.*, Ajudua, Dovlatyan, Duhamel, Howell and Sheikh) knowingly aided and abetted the fraudulent scheme that was perpetrated on GEICO by the Pharmacy Defendants – 21st Century and Alishayev.

211. The acts of the Prescribing Defendants in furtherance of the fraudulent scheme include knowingly purporting to prescribe the Fraudulent Pharmaceuticals and permitting their names to be used in the billing, prescription records and treatment reports submitted in support of the Fraudulent Pharmaceuticals despite their knowledge that 21st Century was ineligible to bill for or to collect No-Fault Benefits in connection with the Fraudulent Services because: (i) it engaged in illegal compounding and manufactured, produced and dispensed vast quantities of the Compounded Products in set formulations, in violation of Federal and New York State regulatory and licensing requirements; (ii) it engaged in unlawful kickback arrangements with licensed physicians; (iii) the billed-for-services were not medically necessary; (iv) the billed-for-services were performed and billed pursuant to a pre-determined, fraudulent treatment and billing protocol designed solely to enrich the Defendants; (v) the Defendants made false and fraudulent misrepresentations to GEICO concerning the maximum permissible charges for the services that purportedly were provided in order to inflate the charges that could be submitted; and (vi) the billed-for-services were provided pursuant to invalid and/or duplicitous prescriptions.

212. The conduct of the Prescribing Defendants in furtherance of the fraudulent scheme was significant and material. The conduct of the Prescribing Defendants was a

necessary part of and was critical to the success of the fraudulent scheme because without their actions, there would be no opportunity for 21st Century to obtain payment from GEICO and from other insurers.

213. The Prescribing Defendants aided and abetted the fraudulent scheme in a calculated effort to induce GEICO into paying charges to 21st Century for medically unnecessary and illusory Fraudulent Pharmaceuticals that were not compensable under the No-Fault Laws, because they sought to continue profiting through the fraudulent scheme.

214. The conduct of the Prescribing Defendants caused GEICO to pay approximately \$2,559,000.00 pursuant to the fraudulent bills that the Defendants submitted or caused to be submitted through 21st Century.

215. The Defendants' extensive fraudulent conduct demonstrates a high degree of moral turpitude and wanton dishonesty that entitles GEICO to recover punitive damages.

216. Accordingly, by virtue of the foregoing, GEICO is entitled to compensatory and punitive damages, together with interest and costs, and any other relief the Court deems just and proper.

SIXTH CAUSE OF ACTION

Against All Defendants (Unjust Enrichment)

217. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

218. As set forth above, the Pharmacy Defendants and the Prescribing Defendants have engaged in improper, unlawful, and/or unjust acts, all to the harm and detriment of GEICO.

219. When GEICO paid the bills and charges submitted by or on behalf of 21st Century for No-Fault Benefits, it reasonably believed that it was legally obligated to make such payments based on the Defendants' improper, unlawful, and/or unjust acts.

220. The Defendants have been enriched at GEICO's expense by GEICO's payments, which constituted a benefit that Defendants voluntarily accepted notwithstanding their improper, unlawful, and unjust billing scheme.

221. Defendants' retention of GEICO's payments violates fundamental principles of justice, equity and good conscience.

222. By reason of the above, the Defendants have been unjustly enriched in an amount to be determined at trial, but in the approximate amount of \$2,559,000.00

JURY DEMAND

223. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demands a trial by jury.

WHEREFORE, Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company and GEICO Casualty Company demand that a judgment be entered in their favor and against the Defendants, as follows:

A. On the First Cause of Action against the Pharmacy Defendants and the Prescribing Defendants, a declaration pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that Defendants, including 21st Century, have no right to receive payment for any pending bills submitted to GEICO;

B. On the Second Cause of Action against Alishayev, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately \$2,559,000.00, together with treble damages, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c) plus interest;

C. On the Third Cause of Action against Alishayev and the Prescribing Defendants, compensatory damages in favor of GEICO in an amount to be determined at trial but

approximately \$2,559,000.00, together with treble damages, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c) plus interest;

D. On the Fourth Cause of Action against the Pharmacy Defendants and the Prescribing Defendants, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately \$2,559,000.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper;

E. On the Fifth Cause of Action against the Prescribing Defendants, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately \$2,559,000.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper; and

F. On the Sixth Cause of Action against the Pharmacy Defendants and the Prescribing Defendants, a recovery in favor of GEICO in an amount to be determined at trial but approximately \$2,559,000.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper.

Dated: Uniondale, New York
August 29, 2016

RIVKIN RADLER LLP

By: _____

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